## REMARKS

Applicant requests that Examiner enter this supplemental amendment, in accordance with MPEP 714.03(a). This supplemental response is limited to the placement of the application in condition for allowance under 37 CFR 1.111(a)(2)(C). No new subject matter has been added.

The claim amendments made in this Supplemental Response are based on the claims filed in the Response to Non-Final Office Action dated March 14, 2008. Claims 1-29, 31-32, 34-35, 37-43, and 67 were pending in this application. Claims 1, 2, 4-5, and 11-12 are currently amended. Claims 13-23, 25-27, 29, and 67 have been cancelled. After entry of this amendment, claims 1-12, 24, 28, 31-32, 34-35, and 37-43 are pending in this application. No new subject matter has been added.

**Examiner's Interview of September 18, 2008**

Applicant thanks the Examiner for the courtesy of the telephonic interview of September 19, 2008 (hereinafter the "interview"). Examiner Gitomer and Applicant's representative, Brian Ho, were present for the interview. All claims were discussed generally in the interview with respect to the Response to Final Office Action and Request for Continued Examination of August 15, 2008. The Applicant's representative briefly discussed the Applicant's plans to file a Supplemental Response to the Final Office Action which is presented below. After examination of the response, the Examiner agreed to further discuss the claims with the Applicant and Applicant's representative in a future interview if the response does not satisfactorily address the outstanding rejections.

**Amendments**

Amendment and/or cancellation of certain claims is in no way an admission or acquiescence to the Examiner's rejection and is not to be construed as a dedication to the public any of the subject matter of the claims as previously presented. No new subject matter has been added.

Claim 1 has been amended to clarify that the method comprises "administering a quantity of $^{2}$H-labeled sugars or $^{2}$H-labeled fatty acids to an individual, said quantity comprising an absolute

amount of $^{2}H$ for a sufficient time for said one or more $^{2}H$-labeled sugars or $^{2}H$-labeled fatty acids to produce $^{2}H$-labeled water" in step (a); "obtaining one or more bodily tissues or fluids at one or more times from said individual, wherein said one or more bodily tissues or fluids comprise a portion of said $^{2}H$-labeled water" in step (b); "detecting $^{2}H$ present in said portion of said $^{2}H$-labeled water to quantify an absolute amount of $^{2}H$ released into body water" in step (c); and "calculating a ratio of said absolute amount of $^{2}H$ released into body water to said absolute amount of $^{2}H$ administered to determine said metabolism of said one or more of sugars or fatty acids in said individual" in step (d). Support for this amendment may be found throughout the specification as originally filed and at least on page 27, lines 13 – 18; page 28, lines 4 – 7; and page 28, lines 11 – 15. Claims 2, 4-5, and 11-12 have been amended to reflect antecedent basis, in view of the amendment to claim 1. No new subject matter has been added.

**Claim Rejections – 35 U.S.C. § 102(b)**

Rittenberg *et al.* (J. of Biol. Chem., 1936, v113, p. 505-510); Rittenberg *et al.* (J. of Biol. Chem., 1937, v117, p. 485-490); and Rittenberg *et al.* (J. of Biol. Chem., 1937, v120, p. 503-510) (hereinafter "each of Rittenberg")

Claims 1, 4-13, 18-24, 28-32 are rejected under 35 U.S.C. § 102(b) as being anticipated by each of Rittenberg. Claims 13, 18-23, and 28-30 have been cancelled.

To anticipate a claim, a cited reference must teach every element of the claim. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987); MPEP § 2131. Each of Rittenberg does not teach "calculating a ratio of said absolute amount of $^{2}H$ released into body water to said absolute amount of $^{2}H$ administered to determine said metabolism of said one or more of sugars or fatty acids in said individual" as presently claimed. Furthermore, each of Rittenberg cannot calculate this ratio with the data they obtained in their experiments without additional data. In order for this ratio to be calculated, the absolute amount of $^{2}H$ released into body water (e.g., in grams or moles) and the absolute amount of $^{2}H$ administered must be known or determined to calculate the ratio recited in the claims. The requisite data are not known or determined in each of

Rittenberg. In each of Rittenberg, the absolute amount of $^2H$ released into body water is not known. Although each of Rittenberg detects $^2H$ present in $^2H$-labeled water, more data is necessary "to quantify an absolute amount of $^2H$ released into body water." Without this data, each of Rittenberg cannot calculate "a ratio of said absolute amount of $^2H$ released into body water to said absolute amount of $^2H$ administered to determine said metabolism of said one or more of sugars or fatty acids in said individual" as presently claimed.

Additionally, in each of Rittenberg, the detection of $^2H$ produced in $^2H$-labeled water was used to qualitatively determine that the $^2H$-labeled water did not reincorporate into the fatty acid products. This is recited, for example, on page 509 of Rittenberg *et al.*, 1936, v113, p. 505-510: "In our experiments the body fluids contained about 0.2 atom per cent of deuterium which came from the breakdown of the ingested fatty acids. Since the deuterium content of the unsaturated fatty acids (0.48 and 1.16 atoms per cent) was from 2 to 5 times as much as the body fluids, it is impossible that the deuterium in these acids came from the water." Therefore, each of Rittenberg uses the $^2H$ produced in $^2H$-labeled water information to make *qualitative* determinations and does not *quantitatively* relate the absolute amount of $^2H$ released into body water to the absolute amount of $^2H$ administered to determine the metabolism of one or more sugars or fatty acids in an individual as presently claimed.

Because each of Rittenberg does not teach every element of the claims, each of Rittenberg is not anticipating prior art. Therefore, Applicant respectfully requests that this basis for rejection be withdrawn.

**Claim Rejections – 35 U.S.C. § 103(a)**

Rittenberg *et al.* (J. of Biol. Chem., 1936, v113, p. 505-510); Rittenberg *et al.* (J. of Biol. Chem., 1937, v117, p. 485-490); and Rittenberg *et al.* (J. of Biol. Chem., 1937, v120, p. 503-510) in view of Jones *et al.* (Am. J. Physiol. Endocrinol. Metab., 2001); (hereinafter "each of Rittenberg in view of Jones")

Claims 1-29, 31, 32, 34, 35, 37-43, and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of each Rittenberg in view of Jones. Claims 13-23, 25-27, 29, and 67 have been cancelled.

For the reasons stated above, each of Rittenberg do not teach or suggest all limitations of what is presently claimed. The addition of the Jones *et al.* reference does not resolve the deficiencies of each of Rittenberg discussed above as they do not teach "calculating a ratio of said absolute amount of $^{2}H$ released into body water to said absolute amount of $^{2}H$ administered to determine said metabolism of said one or more of sugars or fatty acids in said individual." Therefore, it would not be obvious from the cited references to determine *in vivo* metabolism of one or more sugars or fatty acids in an individual using the steps of the presently claimed methods.

Applicant respectfully requests that this basis for rejection be withdrawn.

**Claim Rejections – 35 U.S.C. § 112 – Second Paragraph**

Claims 1-29, 31-32, 34, 35, 37-43, and 67 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the Final Office Action dated May 16, 2008, the Examiner stated that "the addition to the claims of 'one or more mass isotopomers of 2H labeled water' or 'one or more mass isotopomers' is not understood." Claims 13-23, 25-27, 29, and 67 have been cancelled.

Applicant maintains the arguments set forth in the Response to Non-Final Office Action of March 14, 2008 and the Response to Final Office Action of August 15, 2008. However, in the current Supplemental Response, the terms "one or more mass isotopomers of $^{2}H$ labeled water" at issue have been removed from the claims. Accordingly, this basis of rejection is now moot.

In light of the arguments presented above, Applicant respectfully requests that this basis for rejection be withdrawn.

## CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No.: 03-1952** referencing **Docket No.: 416272005200**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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